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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/550,163 | 11/01/2005 | Myong-Ki Jun | 20506/0203371-US0 | 5320 |

7278 7590 11/15/2007

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| EXAMINER | |
|---|---|
| PAPAPIETRO, JACQUELINE M | |
| **ART UNIT** | **PAPER NUMBER** |
| 3739 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 11/15/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/550,163 | JUN, MYONG-KI | |
| | Examiner | Art Unit | |
| | Jacqueline Papapietro | 3739 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *31 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,3-9,15-17 and 21-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-7, 9,15-17 and 21-27* is/are rejected.

7)☒ Claim(s) *8* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 August 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 3, 6, 7, 15, 21, 22, and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ni et al (US 6514251 B1) in view of Schwartz et al (US 6969373 B2).

Regarding claims 1, 3, 21, and 22, Ni discloses an electrode for an electro-surgical operation device, comprising: a hollow electrode (49, Fig 6) formed in a hollow tube shape extending from a closed tip (see Fig 6); a first non-insulation area formed to a predetermined length from the closed tip (column 3 lines 44-46); a first insulation area formed on an outside surface of the hollow electrode beginning a predetermined length from the closed tip (as implied in column 3 lines 44-46); a refrigerant tube (defined as 28 in Figs 3 and 4), having a smaller diameter than a diameter of the hollow electrode, inserted into the hollow electrode (see Fig 6), the refrigerant tube capable of being configured to circulate refrigerants by supplying refrigerants (i.e. 0.9% saturated saline solution, column 3 lines 16-21) from outside of a living body into the hollow electrode to cool living tissue in contact with at least one of the closed tip and the hollow electrode, and by discharging now heat-exchanged refrigerants (see Fig 8) out of the living body (Fig 7); and at least one first hole (or refrigerant discharging mechanism) formed on an outside surface of the first non-insulation area (shown near the tip in Fig 6); the at least one first hole operable to externally discharge a portion of the circulated refrigerants into

the living tissue in contact with the closed tip and/or the hollow electrode (as shown by the arrows running through the holes). Ni discloses the device further comprising: a saline solution pipe (33, Fig 3 and 38, Fig 4) sheathing around the outside surface of the hollow electrode with a predetermined gap (33), and having a second non-insulation area at another predetermined length toward the closed tip (any non-insulation area on the electrode that has not been defined as the first non-insulation area) and a second insulation area on an outside surface of the saline solution pipe except the second non-insulation area (any insulation area not defined as the first insulation area); the saline solution pipe operable to infuse a saline solution through the gap, and discharge the saline solution through at least one second hole (35) formed on an outside surface of the second non-insulation area (column 4 lines 2-7). Ni does not disclose flow control mechanism formed on the outside surface of the first non-insulation area.

Schwartz teaches a hollow catheter with a plurality of holes (66, Fig 11) for injecting a solution into tissue in a predetermined cloud pattern (column 4 lines 31-34). Schwartz teaches a flow control mechanism (76, Fig 11) formed on the outside surface of the catheter in the area of the holes, and operable to act as a discharge resistance to the fluids discharged from the first hole, so as to control a flow of the fluid (column 4 lines 52-58). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have included the flow control mechanism as taught by Schwartz in the invention of Ni in order to better control the cloud pattern of the refrigerant in the tissue to more effectively ablate the tissue.

Regarding claim 6, Ni in view of Schwartz discloses the electrode of claim 1, wherein the closed tip of the hollow electrode (shown as 29 in Fig 3 if Ni) is a conductive spearhead (the closed tapered tip of Ni is interpreted as a spearhead), and the hollow electrode and the spearhead are incorporated with each other (see Figs 3-7).

Regarding claims 7 and 15, Ni in view of Schwartz discloses the electrode of claims 1 and 3, wherein the flow control mechanism is a hollow tube sheathing around the outside surface of the first non-insulation area (Schwartz, Fig 11), and having a third hole on the outside surface (Schwartz, element 84, Fig 11) of the hollow tube, the flow control mechanism controlling a volume of discharged refrigerants by alternately aligning the at least one first hole of the hollow electrode and the third hole of the hollow tube and operating as a discharge resistance to the refrigerants discharged from the at least one first hole (Schwartz, column 17 lines 11-14, see Fig 11).

Regarding claims 26-27, the claimed method is anticipated by the normal use of the device as disclosed by Ni in view of Schwartz.

Claims 9 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ni in view Schwartz as applied to claims 1 and 21 above, and further in view of Brucker et al (US 6017338).

Ni in view of Schwartz discloses the electrode of claims 1 and 21, but does not disclose the flow control mechanism as a porous metal sintered body layer. Brucker teaches an ablation catheter (22) with a central lumen (28) for introducing fluids into the catheter. The tip of the catheter (26) is made of sintered metal which contains a plurality

of randomly formed through-passages and which permits a controlled flow of fluid from the catheter (column 5 lines 30-34) and acts as a discharge resistance mechanism. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Ni in view of Schwartz by forming the flow control mechanism of porous sintered metal in order to obtain a desired discharged fluid profile in the tissue.

Claims 4-5, 16-17, and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ni in view of Schwartz as applied to claims 1, 3, 6, 7, 15, 21, and 22 above, and further in view of Hovda et al (US 2003/0208194 A1).

Ni in view of Schwartz discloses the electrode of claims 3 and 22, with the features described above, wherein the hollow electrode and the saline solution pipe are conductive (Ni, column 3 lines 44-46), further comprising a power source (65, Fig 8) for providing RF electricity (column 4 lines 56-58) and which is capable of being configured to apply different power to the hollow electrode and the saline solution pipe in the form of a bipolar configuration; but does not disclose an insulation member formed on the surface of the hollow electrode to prevent short circuiting. Hovda teaches an electrosurgical device comprising an electrode (104, Fig 12A), and a second conducting member (112) which forms an annular gap (54) which defines a fluid path (83) for a conducting liquid (50, paragraph 0103); an insulation member formed on the surface of the electrode (78) which would prevent short circuit of the saline solution supplied through the gap between the electrode and the saline solution pipe; and an insulation

packing (102) provided between the electrode and the saline solution pipe (Fig 12A). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention as disclosed by Ni in view of Schwartz by including the saline solution pipe and insulation member as taught by Hovda in order to ablate desired tissue in a bipolar configuration and to provide a pathway for electrical current flow between the active and return electrodes.

### *Allowable Subject Matter*

Claim 8 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### *Response to Arguments*

Applicant's arguments filed August 31, 2007 have been fully considered but they are not persuasive.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Examiner

maintains that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included the flow control mechanism as taught by Schwartz in the invention of Ni in order to better control the cloud pattern of the refrigerant in the tissue to more effectively ablate the tissue. Furthermore, Ni discloses the general state of the art in electrosurgical devices with refrigerant tubes and fluid injection modules for the successful ablation of desired tissue. Ni specifically teaches a controlled flow rate (column 4 lines 37-40). Ni does not disclose the technique of controlling the flow with a flow control mechanism formed on the outside surface of the first non-insulation area, and operable to act as a discharge resistance to the refrigerants. Schwartz teaches a system of controlling the flow of solution by including a flow control mechanism formed on the outside surface of the first non-insulation area, and operable to act as a discharge resistance to the refrigerants discharged from a first hole, as described in the rejection above (also see column 16 line 28 – column 17 line 14). Thus, it would have been obvious to one of ordinary skill in the art to apply the technique of the flow control mechanism as taught by Schwartz, to improve the system of Ni for the predictable result of enabling control of the release of refrigerants from the system.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a "high pressure" design, impeding only a portion of the refrigerant) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification,

limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant also argues that Schwartz does not disclose or suggest a flow control mechanism operable to act as a discharge resistance. However, Schwartz clearly teaches a flow control mechanism operable to act as a discharge resistance. Figure 11 clearly shows that when the flow control mechanism is in place (shown in phantom), the control mechanism covers some holes and opens others, releasing only a portion of the fluid through the holes, thereby controlling the flow and acting as a discharge resistance.

### *Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline Papapietro whose telephone number is (571) 272-1546. The examiner can normally be reached on M-F 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JMP

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